



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Recombinant Chimeric Bovine/Human Parainfluenza Virus 3 Expressing SARS-CoV-2 Spike Protein and its Use

Description of Technology:

Vaccines for SARS-CoV-2 are increasingly available under emergency use authorizations; however, indications are currently limited to individuals twelve (12) years or older. They also involve intramuscular immunization, which does not directly stimulate local immunity in the respiratory tract, the primary site of SARS-CoV-2 infection, shedding and spread. While the major burden of COVID-19 disease is in adults, infection and disease also occur in infants and young children, contributing to viral transmission. Therefore, the development of safe and effective pediatric COVID-19 vaccines is important. Ideally, a vaccine should be effective as a single dose, should induce mucosal immunity with the ability to restrict SARS-CoV-2 infection and respiratory shedding, and should easily coordinate with vaccines for other illnesses, such as HPIV3.

The live-attenuated vaccine candidates are based on a recombinant chimeric bovine/human parainfluenza virus 3 (rB/HPIV3) vector expressing prefusion-stabilized versions of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Spike (S) protein. The B/HPIV3-SARS CoV-2 vaccine candidates are designed to be administered intranasally by drops or spray to infants and young children. The vaccines are expected to induce durable and broad systemic and respiratory mucosal immunity against SARS-CoV-2 and HPIV3. Immunogenicity and protective efficacy against SARS-CoV-2 challenge was confirmed in experimental animals including non-human primates. Based on experience with this B/HPIV3 platform and other live-attenuated PIV vaccine candidates in previous pediatric clinical studies, the present candidates are anticipated to be well-tolerated in humans, including infants and young children, and are available for clinical evaluation. The National Institute of Allergy

and Infectious Diseases has extensive experience and capability in evaluating live-attenuated respiratory virus vaccine candidates in pediatric clinical studies, including PIV vaccine candidates, and opportunity for collaboration exists.

This technology is available for nonexclusive licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Viral diagnostics
- Vaccine research

Competitive Advantages:

- Ease of manufacture
- B cell and T cell activation
- Low-cost vaccines
- Intranasal administration/needle-free delivery

Development Stage:

- *In vivo* data assessment (animal)

Inventors: Ursula Buchholz (NIAID), Shirin Munir (NIAD), Cyril Le Nouen (NIAID), Xueqiao Liu (NIAID), Cindy Luongo (NIAID), Peter Collins (NIAID).

Intellectual Property: HHS Reference No. E-239-2020-0 - U.S. Provisional Application No. 63/180,534, filed April 27, 2021

Licensing Contact: Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov.

Dated: May 10, 2021.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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